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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,096	02/01/2001	Dan Nilsson	54337.000009	6906
21967 7590 03/24/2009 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT 1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109				
EXAMINER				
STEADMAN, DAVID J				
ART UNIT		PAPER NUMBER		
1656				
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03/24/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/720,096

Applicant(s)

NILSSON ET AL.

Examiner

David J. Steadman

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005 and 08 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 9-12, 17, 24 and 28-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1, 9-12, 17, 24 and 28-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

- [1] Claims 1, 9-12, 17, 24, and 28-32 are pending in the application.
- [2] Applicants' amendment to the claims, filed on 1/8/09, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3] Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, and a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, all filed on 1/4/08, is acknowledged.
- [4] Receipt of information disclosure statements, filed on 3/2/05 and 8/28/06 is acknowledged.
- [5] In the interest of compact prosecution, it is noted that SEQ ID NO:10 is listed as being DNA derived from both *Streptococcus thermophilus* and *Phaffia rhodozyma* in claim 12. In the event that this is an inadvertent typographical error, for purposes of restriction, the examiner has grouped the *Streptococcus thermophilus* DNA and the *Phaffia rhodozyma* DNA in separate groups (Groups III and IV, respectively, below). In the event that that the *S. thermophilus* AND *P. rhodozyma* DNA are both intended as being SEQ ID NO:10, the restriction between Groups III and IV may be withdrawn. Applicant's clarification is requested.

Sequence Compliance

[6] In order to perfect the requirements for a sequence listing, applicant is required to submit an amendment to the specification, requesting entry of the sequence listing paper copy filed on 1/4/08 into the application. Applicant's attention is directed to the "Notice to Comply" mailed on 12/10/07, box 2 under "Applicant Must Provide", which states, "An initial or substitute paper copy of the 'Sequence Listing', *as well as an amendment directing its entry into the specification*" (emphasis added).

Election/Restriction

[7] In the response filed on 10/11/05, applicant notes that the restriction requirement mailed on 8/10/05 is improper in-part because the examiner has failed to identify linking claims. Applicant's argument is persuasive and a new restriction requirement is set forth below to address applicant's concern. The instant restriction requirement employs linking claims analysis in accordance with MPEP 809.

According to MPEP 803.01, a restriction requirement is at the discretion of the examiner and according to 37 CFR 1.142(a), a requirement for restriction "may be made at any time before final action." See also MPEP 811.02, which states, "[s]ince 37 CFR 1.142(a) provides that restriction is proper at any stage of prosecution up to final action, a second requirement may be made when it becomes proper, even though there was a prior requirement with which applicant complied. *Ex parte Benke*, 1904 C.D. 63, 108 O.G. 1588 (Comm'r Pat. 1904)."

[8] Claim 1 link(s) inventions I to V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the

indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

[9] Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 9-12, 17, 24, and 28-32, drawn to methods using an auxotroph transformed with a plasmid comprising *Lactococcus lactis subsp. Cremoris* DNA having the sequence of SEQ ID NO:7, classified in class 426, subclass 34.
- II. Claims 9-12, 17, 24, and 28-32, drawn to methods using an auxotroph transformed with a plasmid comprising *Lactococcus lactis subsp. lactis*

DNA having the sequence of SEQ ID NO:8, classified in class 426, subclass 34.

- III. Claims 9-12, 17, 24, and 28-32, drawn to methods using an auxotroph transformed with a plasmid comprising *Streptococcus thermophilis* DNA having the sequence of SEQ ID NO:10, classified in class 426, subclass 34.
- IV. Claims 9-12, 17, 24, and 28-32, drawn to methods using an auxotroph transformed with a plasmid comprising *Phaffia rhodozyma* DNA having the sequence of SEQ ID NO:10, classified in class 426, subclass 34.
- V. Claims 9-12, 17, 24, and 28-32, drawn to methods using an auxotroph transformed with a plasmid comprising *Trichoderma reesei* DNA having the sequence of SEQ ID NO:11, classified in class 426, subclass 34.

[10] The inventions are distinct, each from the other because:

[11] The methods of Groups I to V are related as being methods of fermenting milk using a purine or thymidine auxotroph. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, since each of the DNAs as recited in claim 12 is structurally distinct, the inventions as claimed each uses a distinct auxotrophic bacterium and thus each of the inventions of Groups I to V has a materially

different design. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

[12] Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David J. Steadman/
Primary Examiner, Art Unit 1656